| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 44D2083451 | 02/08/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Grace Pediatrics, Pllc | 990 Ellison Way, Suite 100, Thompsons Station, TN | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of 2016 and 2017 Proficiency Testing (PT) attestation records and an interview with the lead nurse testing person, it was determined the laboratory did not involve all 6 testing personnel in rotating PT samples for complete blood counts during the 2 year period. Findings include: 1. A review of PT attestation records from 2016 and 2017 disclosed the primary lab person did all testing of PT samples. 2. An interview with the lead nurse testing person at 11 AM on February 8, 2018 confirmed that only the primary testing person was running PT samples for the 2 year period. |
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of Proficiency Testing (PT) records from 2016-2017 and interview with the lead nurse testing person, determined the PT attestation statements were not signed by the lab director or technical consultants during the two year period. Findings include: 1. A review of PT records for 2016 to 2017 disclosed the laboratory director or technical consultants did not sign the attestation statements for each event during the two year period. 2. An interview with the lead nurse testing person at approximately 9:45 AM on February 8, 2018, confirmed the laboratory director and/or technical consultants did not sign the attestation statements for each event during the two year period. |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.<br><br>This CONDITION is not met as evidenced by:<br>The laboratory failed to maintain satisfactory participation in two out of three events for the automated red blood cell (RBC) differential, resulting in the first unsuccessful proficiency testing (PT) occurrence for the automated WBC differential analyte. (Refer to D2130) |
| **D2130** | HEMATOLOGY<br>CFR(s): 493.851(f)<br><br>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on a desk review of the CMS 155 report and the laboratory's 2017 PT records, the laboratory failed to maintain satisfactory performance for the automated RBC analyte in 2017 event one and event two, resulting in the first unsuccessful occurrence. The findings include: 1) Review of the CMS 155 report revealed the automated RBC 2017 event one score is 60% and the 2017 event two score is 60%. 2) Review of the laboratory's 2017 event one PT reports revealed sample numbers HEM- |

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| | 01 and HEM-02 were Unacceptable, resulting in a score of 60%. 3) Review of the laboratory's 2017 event two PT reports revealed sample numbers HEM-06 and HEM-10 were Unacceptable, resulting in a score of 60%. |
| **D3039** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(5)<br><br>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the quality assurance (QA) plan and Quality Control (QC) records and interview with the lead nurse testing person determined the laboratory failed to retain all Quarterly Quality Control Checklist records for at least two years in 2016-2017. The findings include: 1. Review of the QA plan revealed the requirement under Quality Control Assessment for "The laboratory director reviews all quality control logs on a quarterly basis." 2. Review of the QC records revealed no Quarterly QC Checklists performed for the 2nd-4th quarters of 2016 and 1st-3rd quarters of 2017. 3. Interview with the lead nurse testing person on February 8, 2018, at approximately 11:00 AM confirmed that the laboratory director did not retain the Quarterly QC Checklists for the 2nd-4th quarters of 2016 and 1st-3rd quarters of 2017. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's procedure manual and upon interview with the lead nurse testing person, determined the laboratory manual failed to include panic or alert values for the Complete Blood Count (CBC) procedure for 2017. The findings include: 1. A review of the laboratory's procedure manual for 2017 revealed no panic or alert values included in CBC testing. 2. An interview at approximately 11:30 a.m. on February 8, 2018, with the lead nurse testing person, confirmed there were no panic or alert values included in the procedure manual for CBC testing for 2017. |

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| **D5463** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(7)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--<br>Over time, rotate control material testing among all operators who perform the test.<br>(g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of Quality Control (QC) records from 2016-2017 and interview with the lead nurse testing person, determined the Complete Blood Count (CBC) QC material was only performed by 2 of 6 testing persons during the two year period. Findings include: 1. A review of Quality Control (QC) records from 2016-2017 disclosed only the two lead testing persons (#2 & #5) were performing CBC QC during the two year period. 2. An interview with the lead nurse testing person at approximately 10:00 AM on February 8, 2018, confirmed only the two lead testing persons (#2 & #5) were performing CBC QC during the two year period. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of 6 of 6 testing personnel competency documents for performing Complete Blood Counts (CBC) and upon interview with the lead nurse testing person, determined the technical consultants failed to ensure documented annual competency evaluations of all testing personnel for 2016-2017. The findings include: 1. There were no competency evaluations documented/signed for 6 of 6 testing personnel in 2016-17 for performance of CBC testing. 2. Interview with the lead nurse testing person at approximately 11:30 a.m. on February 8, 2018, confirmed the Technical Consultants failed to document/sign competency assessments for 6 of 6 testing persons in 2016-17 for CBC testing. |